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SENATE BILL 1730 By
Ford J

HOUSE BILL 1746
By Armstrong

AN ACT to amend Tennessee Code Annotated, Title 47; Title 53; Title 56; Title 63, Title 65, Title 68 and Title 71, relative to prescription drugs.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 68, is amended by adding Sections 2 through 6, inclusive, as a new chapter to be appropriately designated.

SECTION 2.

(a) The price regulation program established by this act, referred to in this part as the "program," is established to reduce prescription drug prices for residents of the State.

(b) The general assembly finds that affordability is critical in providing access to prescription drugs for Tennessee residents. This part is enacted by the general assembly to enable the State to act in order to make prescription drugs more affordable for Tennessee residents, thereby increasing the overall health of Tennessee residents, promoting healthy communities and protecting the public health and welfare. It is not the intention of the State to discourage employers from offering or paying for prescription

drug benefits for their employees or to replace employer-sponsored prescription drug benefit plans.

(c) As used in this part, unless the context otherwise indicates, the following terms have the following meanings:

(1) "Commissioner" means the commissioner of health.

(2) "Department" means the department of health.

(3) "Participating retail pharmacy" or "retail pharmacy" means a retail pharmacy located in this State, or another business licensed to dispense prescription drugs in this State.

(4) "Prescription drug" means any item which federal law prohibits dispensing without a prescription from a licensed doctor, dentist, optometrist or veterinarian.

SECTION 3.

(a) The prescription drug advisory commission, referred to in this part as the "commission," is established to review access to and the pricing of prescription drugs for residents of the State, to advise the commissioner on prescription drug pricing and to provide periodic reports to the commissioner, the governor and the general assembly.

(b) The commission consists of the following twelve (12) members:

(1) Three (3) members of the public, appointed by the speaker of the senate, one of whom must represent the interests of senior citizens. Of the initial appointees, one (1) must be appointed for a two (2) year term and (two) 2 for three (3) year terms;

(2) Three (3) members of the public, appointed by the speaker of the house of representatives, one of whom must represent the interests of senior citizens. Of the initial appointees, one (1) must be appointed for a two (2) year term and (two) 2 for three (3) year terms;

(3) Two (2) members of the health care community who are authorized by the laws of this State to prescribe drugs, appointed by the governor. Of the initial appointees, one (1) must be appointed for a two (2) year term and one for a three (3) year term;

(4) Two (2) pharmacists appointed by the governor. Of the initial appointees, one (1) must be appointed for a two (2) year term and one (1) for a three (3) year term. To be appointed to and remain on the commission, each pharmacist must:

(A) Be licensed to practice pharmacy and be engaged in the practice of retail pharmacy in this State;

(B) Have at least five (5) years of experience in this State as a licensed pharmacist; and

(C) Be a resident of this State; and

(5) The director of the bureau of TennCare and the commissioner of health, or their designees, who shall serve as ex officio, nonvoting members.

(c) With the exception of the initial appointees, all members of the commission serve for terms of three (3) years and may be reappointed. With the exception of the pharmacist members, if the profession or qualifications of a commission member changes during the term of commission membership, the member may continue to complete the term for which the appointment was made.

(d) The commission shall meet at least four (4) times per year. The members shall select a chair from among the members. Additional meetings may be called by the chair.

(e) The duties of the commission include the following:

(1) To review access to prescription drugs for residents of the State, including, but not limited to, pricing and affordability information;

(2) To advise the commissioner on access to prescription drugs and prescription drug prices, including, but not limited to, insurance and third-party payments for prescription drugs, the need for maximum retail prices, and, if maximum retail prices are established, the procedures for adoption and periodic review of maximum retail prices, the procedures for establishing maximum retail prices for new prescription drugs and for reviewing maximum retail prices of selected drugs and the procedures for phasing out or terminating maximum retail prices;

(3) To advise the commissioner on the adoption of rules necessary to implement this part; and

(4) To report to the commissioner, the general assembly and the governor by April 1, 2002, and annually thereafter by the second week in January, including in the report any recommendations for action regarding access to, and the pricing of, prescription drugs.

(f) The department shall provide staffing for the commission.

(g) Public members not otherwise compensated by their employers or, other entities whom they represent, are entitled to receive reimbursement for their attendance at authorized meetings of the commission in accordance with the rules promulgated by the commissioner of finance and administration and approved by the attorney general and reporter.

(h) In performing its duties, the commission shall work with the department, the board of pharmacy and the department of commerce and insurance.

SECTION 4.

(a) In order to achieve the public health purposes listed in Sections 2 and 8 of this act, maximum retail prices for prescription drugs sold in Tennessee may be established pursuant to this section.

(b) The following provisions apply to determinations regarding maximum retail prices for prescription drugs and to the procedures for establishing those prices.

(1) By July 1, 2003, the department shall adopt rules establishing the procedures for adoption and periodic review of maximum retail prices, the procedures for establishing maximum retail prices for new prescription drugs and for reviewing maximum retail prices of selected drugs and the procedures for phasing out or terminating maximum retail prices. Prior to adopting rules pursuant to this section, the commissioner shall consult with and consider the recommendations of the commission regarding the rules.

(2) By January 1, 2004, the commissioner shall determine whether the cost of prescription drugs provided to residents under the medical assistance program is reasonably comparable to the lowest cost paid for the same drugs delivered or dispensed in the State. In making this determination the following provisions apply:

(A) The commissioner shall review prescription drug use in the medical assistance program using data from the most recent six (6) month period for which data is available.

(B) Using the data reviewed in subdivision (A), the commissioner shall determine the one hundred (100) drugs for which the most units were provided and the one hundred (100) drugs for which the total cost was the highest.

(C) For each prescription drug listed in subdivision (B), the commissioner shall determine the cost for each drug for residents provided those drugs under the medical assistance program on a certain date. The average cost for each such drug must be calculated.

(D) For each prescription drug listed in subdivision (C), the commissioner shall determine the lowest cost for each drug paid by any purchaser on the date that is used for subparagraph (3) delivered or dispensed in the State, taking into consideration the federal supply schedule and prices paid by pharmaceutical benefits managers and by large purchasers and excluding drugs purchased through the medical assistance program. The average cost for each such drug must be calculated.

(E) If the average cost for one (1) or more prescription drugs under the medical assistance program as determined in subdivision (C) is not reasonably comparable to the average lowest cost for the same drug or drugs as determined in subdivision (D), the commissioner shall establish maximum retail prices for any or all prescription drugs sold in the State. Maximum prescription drug prices established under this subparagraph shall take effect July 1, 2004.

(3) In establishing maximum retail prices under this paragraph, the commissioner shall consider the advice of the commission and shall follow procedures set forth by rules adopted by the department.

(c) In making a determination under this section the commissioner may rely on pricing information on a selected number of prescription drugs if that list is representative of the prescription drug needs of the residents of the State and is made public as part of the process of establishing maximum retail prices.

(d) The commissioner may take actions that the commissioner determines necessary if there is a severe limitation or shortage of, or lack of, access to prescription drugs in the State that could threaten or endanger the public health or welfare.

(e) A retailer of prescription drugs may appeal the maximum retail price of a prescription drug established pursuant to this section in accordance with the Uniform Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

(f) A violation of the maximum retail prices established under this section is a violation of the Tennessee Unfair Trade Practices Act and shall be subject to enforcement in the same manner violations of Tennessee Code Annotated, Sections 47-25-101 and 47-25-102.

SECTION 5. Tennessee Code Annotated, Title 47, is amended by adding Sections 6 through 9, inclusive as a new part 18.

SECTION 6.

(a) The general assembly makes the following findings:

(1) Pharmaceutical companies are charging the citizens of Tennessee excessive prices for prescription drugs, denying Tennessee citizens access to medically necessary health care and thereby threatening their health and safety. Many Tennessee citizens are admitted to or treated at hospitals each year because they cannot afford the drugs prescribed for them that could have prevented the need for hospitalization. Many others must enter expensive institutional care settings because they cannot afford their necessary prescription drugs that could have supported them outside of an institution. All Tennessee citizens are threatened by the possibility that when they need medically necessary prescription drugs most they may be unable to afford their doctor's recommended treatment.

(2) Citizens of Tennessee and other Americans pay the highest prices in the world for prescription drugs, prices that result in extremely high profits for pharmaceutical companies.

(3) Prescription drug costs represent the fastest growing item in health care and are a driving force in rapidly increasing hospital costs and insurance rates.

(4) Excessive pricing for prescription drugs threatens Tennessee's ability to assist with the health care costs of Tennessee citizens, undermines the financial capacity of Tennessee communities to meet the educational needs of Tennessee children, hurts the ability of the Tennessee business community to provide health insurance coverage to Tennessee's work force and has a negative effect on Tennessee's economy. The general assembly finds that affordability is critical in providing access to prescription drugs for Tennessee residents.

(b) It is the intent of the general assembly to provide access for all Tennessee citizens to medically necessary prescription drugs at the lowest possible prices.

(c) This act is enacted by the general assembly as a positive measure to make prescription drugs more affordable for Tennessee residents, thereby increasing the overall health of our families, benefiting employers and employees and the fiscal strength of our society, promoting healthy communities and increasing the public health and welfare.

SECTION 7. Profiteering in prescription drugs is unlawful and is subject to the provisions of this section. The provisions of this section apply to manufacturers, distributors and labelers of prescription drugs.

(a) As used in this part, unless the context otherwise indicates, the following terms have the following meanings:

(1) "Labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the federal Food and Drug Administration under 21 Code of Federal Regulations, 207.20.

(2) "Manufacturer" means a manufacturer of prescription drugs and includes a subsidiary or affiliate of a manufacturer.

(b) A manufacturer, distributor or labeler of prescription drugs engages in illegal profiteering if that manufacturer, distributor or labeler:

(1) Exacts or demands an unconscionable price;

(2) Exacts or demands prices or terms that lead to any unjust or unreasonable profit;

(3) Discriminates unreasonably against any person in the sale, exchange, distribution or handling of prescription drugs dispensed or delivered in the State; or

(4) Intentionally prevents, limits, lessens or restricts the sale or distribution of prescription drugs in this State in retaliation for the provisions of this part.

(c) The attorney general and reporter may bring a civil action in chancery court or circuit court for a direct or indirect injury to any person, group of persons, the State or a political subdivision of the State caused by a violation of this part. There is a right to a jury trial in any action brought in chancery court under this section. If the State prevails, the defendant shall pay three (3) times the amount of damages and the costs of suit, including necessary and reasonable investigative costs, reasonable expert fees and reasonable attorney's fees. For a willful or repeated violation of this section, punitive damages may be awarded. After deduction of the costs of distribution, the damages must be equitably distributed by the State to all injured parties.

(d) Each violation of this section is a civil violation for which the attorney general and reporter may obtain, in addition to other remedies, injunctive relief and a civil penalty in an amount not to exceed one hundred thousand dollars ($100,000), plus the costs of

suit, including necessary and reasonable investigative costs, reasonable expert fees and reasonable attorney's fees.

(e) A violation of this section is also a violation of the Unfair Trade Practices Act, Tennessee Code Annotated, Title 47, Chapter 25, Part 1, and shall be subject to enforcement in the same manner as violations of Sections 47-25-101 and 47-25-102.

SECTION 8. The attorney general and reporter, upon the attorney general and reporter's own initiative, or upon petition of the commissioner of health or of fifty (50) or more residents of the State, shall investigate suspected violations of this part.

The attorney general and reporter may require, by summons, the attendance and testimony of witnesses and the production of books and papers before the attorney general related to any such matter under investigation. The summons must be served in the same manner as a summons for witnesses in criminal cases, and all provisions of law related to criminal cases apply to any summons issued under this section so far as they are applicable. All investigations or hearings under this section to which witnesses are summoned or called upon to testify or to produce books, records or correspondence are public or private at the choice of the person summoned and must be held in the county where the act to be investigated is alleged to have been committed, or if the investigation is on petition, it must be held in the county in which the petitioners reside.

The court may by order, upon application of the attorney general and reporter, compel the attendance of witnesses, the production of books and papers, including correspondence, and the giving of testimony before the attorney general and reporter in the same manner and to the same extent as before the court. Any failure to obey such an order may be punishable by that court as a contempt.

SECTION 9. The State may negotiate and enter into purchasing alliances and regional strategies with the governments of other jurisdictions and with other public and private entities for the purpose of reducing prescription drug prices for residents of the State.

SECTION 10. The provisions of this act shall be construed to apply to and affect only entities which furnish products or services within the state, and this chapter shall not be construed to extend to any entity engaged in interstate commerce the regulation of which jurisdiction is vested in a federal board or commission.

SECTION 11. The provisions of this act shall not be construed to be an appropriation of funds and no funds shall be obligated or expended pursuant to this act unless such funds are specifically appropriated by the general appropriations act.

SECTION 12. The commissioner of health is authorized to promulgate rules and regulations to effectuate the purposes of this act. All such rules and regulations shall be promulgated in accordance with the provisions of Tennessee Code Annotated, Title 4, Chapter 5.

SECTION 13. If any provision of this act or the application thereof to any person or circumstance is held invalid, such invalidity shall not affect other provisions or applications of the act which can be given effect without the invalid provision or application, and to that end the provisions of this act are declared to be severable.

SECTION 14. This act shall take effect July 1, 2001, the public welfare requiring it.